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10/687,850	10/17/2003	David W. Burke	7404-558	9581

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1795

MAIL DATE	DELIVERY MODE
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02/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/687,850	Applicant(s) BURKE ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12/29/2008 (RCE).
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 7-15 is/are allowed.
- 6) Claim(s) 1-6 and 16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is supplemental to the one prepared yesterday, on February 02, 2009. That Office action inadvertently contains a draft copy of the Office action. In particular, some of the items are misnumbered and the status of the previously pending claims are not identified.

Status of the Rejections Pending Since the Office action of June 25, 2008 (Final Rejection)

2. All previous rejections are withdrawn.

Response to Arguments

3. Applicant's arguments filed December 29, 2008 ("Amendment") have been fully considered but they are not persuasive. The Examiner acknowledges that Neel only applies a DC signal to the second pair of electrodes in his test strip. The Examiner also acknowledges that Beaty applies an AC signal or an AC signal with DC offset, that is, a signal having an AC component, to a test strip having only one pair of electrodes. The Examiner also agrees that one reason, although not the only reason, Neel uses a separate pair of electrodes to determine sample volume sufficiency to avoid perturbing

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the sample before measurement. The Examiner does not agree, though, that Beaty is incompatible with Neel.

Even, *arguendo*, Applicant is correct in stating, "There is no teaching in Beaty of using a DC offset during the sample volume determination" (top of page 11 of the Amendment) there is still motivation to provide a signal having an AC component to the second pair of electrodes in Neel. Indeed, Applicant provides the motivation, "It is well known in the art that a DC bias voltage on the sample/reagent is to be avoided until it is desired to begin the analyte measurement test to determine the Cottrell decay curve." Applicant then cites several patents in support of this assertion. See the bottom of page 8 of the Amendment, bridging to page 9. So, the second pair of electrodes allows for determining sample volume using an AC component while also allowing determining the concentration of the interferants with a DC bias, as taught by Beaty, without perturbing the sample. Applicant alleges that both the AC component and DC bias are used to determine the concentration of the interferants. See the bottom of page 10 of the Amendment. However, the Examiner respectfully disagrees. The low magnitude AC voltage excitation voltage referred to in column 11, lines 32-46 in Beaty clearly can be used for sample identity, *sample volume*, sample temperature/hematocrit, ... See the immediately preceding paragraph, col. 11:17-31. A fair reading of col. 11:16-46 in the Examiner's view teaches that the DC bias is used to determine the concentration of the interferants. Even, *arguendo*, Applicant's interpretation is correct, which the Examiner does not concede, it is moot because (1) there is still the benefit of a having a second pair of electrodes to avoid perturbing the sample when making measurements other

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than for measuring the analyte of interest, and (2) none of claims 1-6 require that the second test signal is measuring sample volume. The information gleaned from the second response is not limited at all.

For the reasons set forth above, Applicant's arguments with regard to the rejections of claims 1-6 and 16 are not persuasive.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. (US 6,645,368 B1) ("Beaty") and Ohara et al. US 6,193,873 B1 ("Ohara").

Addressing claim 1, Neel discloses a method of performing a measurement on a biological fluid in a test strip (abstract) comprising

providing a biological fluid test strip (10) including

a capillary fill chamber (66) extending a length along the test strip from an intake opening (68) to a terminus (70)(Figures 1-3),

a first pair of electrodes (22,24) in operative communication with the chamber (Figure 2),

and

a second pair of electrodes (28,30) in operative communication with the chamber (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to flow from the intake opening toward the terminus (col. 14:43-51);

applying a first test signal to at least one of the first pair of electrodes (col. 14:48-55);

measuring a first response to the first test signal (col. 14:48-55);

maintaining the first pair of electrodes in an inoperative state after the measuring the first response (col. 14:55-57);

applying a second test signal to at least one of the second pair of electrodes (col. 14:67 – col. 15:03);

measuring a second response to the second test signal (col. 14:67 – col. 15:03); and

performing a measurement upon the biological fluid after the measuring the second response (col. 15:26-28).

The second test signal applied by Neel appears to be just a DC test signal (col. 14:67 – col. 15:03).

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Beaty discloses applying an AC test signal to test electrodes to determine sample volume sufficiency and/or other parameters, such as sample temperature, and sample identity/hematocrit in an electrochemical test strip for determining the concentration of a medically significant component of a biological fluid. See the abstract; Figure 2; col. 06:20-42; and col. 11:16-30. The AC test signal may have DC bias to allow the determination of concentration of interferants of interest.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal or a signal having both an AC component and a DC component as taught by Beaty in the invention of Neel as the second test signal because as taught by Beaty with an AC signal both sample identity and sample volume can then be determined with little affect from hematocrit, glucose (or other analyte) concentration, temperature, bilirubin concentration, uric acid concentration, and oxygen concentration; and with an additional DC bias in the second signal the concentrations of interferants may be determined without perturbing the sample. See 06:20-42 and col. 11:16-44. Moreover, as shown by Ohara it was known at the time of the invention that measurements other than for analyte concentration should not perturb the sample: "For accurate results, the sample detection procedure should not perturb the analyte concentration, ..." See col. 02:01-4.

Addressing claim 2, Neel et al discloses the measuring of the first response to

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the first test signal is indicative of contact between the first pair of electrodes and the biological fluid (Column 14, lines 48-51).

Addressing claim 3, Neel et al discloses measuring the first response to the first test signal to indicate contact of the first pair of electrodes and the fluid (Column 14, line 63 through Column 15, line 11).

Addressing claim 4, Neel et al discloses measuring the second response to the second test signal to indicate contact of the second pair of electrodes and the fluid (Column 14, lines 48-55).

Addressing claim 5, Neel et al discloses performing a measurement on the biological fluid by applying a test signal to at least one of the first pair of electrodes (Column 15, lines 47-58).

Addressing claim 16, for the additional limitation of this claim note that Beaty teaches that the second test signal may be a pure AC signal or may have a DC offset. See col. 06:20-57 and col. 11:32-36.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. US 6,743,635 B2 ("Neel") in view of Beaty et al. US 6,645,368 B1 ("Beaty") as applied to claims 1-5 and 16 above, and further in view of Feldman et al. US 6,592,745 B1 ("Feldman").

Neel does not mention providing a third pair of electrodes in operative communication with the chamber wherein the performing a measurement upon the biological fluid includes applying a measurement test signal to at least one of the third pair of electrodes.

Feldman discloses an electrochemical biosensor for performing a measurement on a biological fluid. The biosensor comprises multiple working electrodes (42, 44, 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (col. 49:7-12). It would have been obvious to provide at least one additional pair of electrodes, to form a third electrode pair, as taught by Feldman in the invention of Neel as modified by Beaty

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because as taught by Feldman, "... multiple electrode sensors may be used to test a variety of analytes using a single sample ..." and "[m]ultiple electrode sensors may also be used to improve the precision of the resulting readings ...". See col. 48:16-59.

Allowable Subject Matter

7. Claims 7-15 are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguera/
Primary Examiner, Art Unit 1795
February 3, 2009